

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS OF THE POLICY INCORPORATED BY REFERENCE BY
SECTION 100800**

HEARING DATE: None scheduled.

DEADLINE FOR SUBMISSION OF COMMENT: August 22, 2011

SUBJECT MATTER OF PROPOSED AMENDMENTS: Acceptable Research Materials

SECTIONS AFFECTED: The proposed amendments apply to Chapter 2 and section 100800 of Title 17 of the California Code of Regulations, and specifically the document incorporated by reference therein.

DOCUMENT INCORPORATED BY REFERENCE BY SECTION 100800:

CIRM LOAN ADMINISTRATION POLICY

CHAPTER I –INCORPORATION BY REFERENCE:

C. Defined Terms

Purpose: The definitions contained in this section shall apply to their respective terms used in the policy.

Change of Control: A sale, merger, transfer, exchange or other disposition (whether of assets, stock or otherwise) of a majority or controlling ownership position.

Company-Backed Loan: A loan which the Loan Recipient organization is obligated to repay, notwithstanding the success of the CIRM-funded project.

Product-Backed Loan: A Loan which the Loan Recipient organization is obligated to repay, subject to suspension or forgiveness of all or part of the loan based on the success of the CIRM-funded project.

Rationale: To make specific the language and terminology used in formulating these regulations.

V. PAYMENT AND USE OF FUNDS

...

D. Prior Approval Requirements

5. Relinquishment of Award and Award Transfer

Purpose: The amendments provide that in the event that Loan Recipient is acquired by merger, purchase or otherwise after completion of the research described in the Notice of Loan Award, the successor in interest shall have the same obligations as the Loan Recipient under the Loan Administration Policy.

The assignee of any CIRM Funded Invention shall have the same obligations as the Loan Recipient under the Loan Administration Policy

Any such assignment or transfer to a successor in interest shall be subject to CIRM's prior written approval which shall not be unreasonably withheld.

Rationale: This provision ensures that in the common event of merger or other form of acquisition that it is clear that the provisions of the loan award apply to the acquiring entity. Assignment or transfer to the successor in interest shall be subject to CIRM's prior consent to ensure that the transferee is capable of fulfilling the obligations borne under the Loan Agreement.

H. Reporting Requirements

...

5. Reporting Related to Loan Terms

Purpose: This section states that in addition to other reporting requirements, Loan Recipients and Borrowers must notify CIRM of any Change in Control. Loan Recipients and Borrowers shall also report initial public offerings and follow-on financing.

Rationale: In light of the deletion of provisions involving "loan acceleration," this section is amended to reflect the introduced term "Change in Control" as a matter about which the Loan Recipients and Borrowers must notify CIRM. This reporting requirement ensures CIRM is able to assure compliance with substantive provisions of the policy regarding "Change of Control."

VII. LOAN TERMS

A. Company-Backed and Product-Backed Loans

Purpose: The amendments add language stating that "Success" means that the Loan Recipient has obtained revenue arising in whole or in part from the CIRM-Funded Project. To the extent that a Loan Recipient has obtained revenue arising in whole or in part from the CIRM-Funded Project in an amount less than the loan amount, the Loan Recipient shall be required to repay CIRM the principal and interest on the loan up to the amount of revenue generated.

The amendments also provide that the following are guidelines for loan terms. Specific terms will be determined in each RFA by the Finance Subcommittee of the ICOC, based on the recommendation of the President, as appropriate for each RFA. If the Finance

Subcommittee does not modify these guidelines for a specific RFA, the terms set forth herein shall apply to the RFA. However, the loan terms may be modified in a loan agreement provided that the Loan Recipient agrees to the modifications and the Finance Subcommittee approves them.

Rationale: These amendments clarify that CIRM is entitled to any revenues which arise in whole or in part from a CIRM-funded project. This definition is necessary to ensure the CIRM receives the revenue it is due from revenue that arises as a result of its funding. The amendments also provide valuable flexibility to allow the Loan Recipient and CIRM to adjust the loan terms upon agreement to address unforeseen circumstances.

B. Interest Rate

Purpose: The amendments provide that the interest rate for a 5 year loan term shall be a per annum rate equal to the London Inter-Bank Offered Rate (“LIBOR”) for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or if the Wall Street Journal is not available, a comparable source) on the date of the first disbursement, plus two percent (2%). On the date of each subsequent disbursement, the applicable interest rate shall be a per annum rate equal to LIBOR for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or comparable source) on such date, plus two percent (2%). The rate established for each disbursement shall apply only to that disbursement and not to the amount outstanding before such disbursement. Interest shall be compounded annually on the principal amount disbursed by CIRM from the date of the applicable disbursement to Loan Recipient.

Rationale: These amendments clarify the mechanism for determining the interest rate owed on a loan and how that figure is calculated. These amendments are necessary to provide clarity on how interest is calculated.

C. Warrants

Purpose: The amendments provide that:

1. Requirement

a. Company-Backed Loans: Except as provided in subpart “D” of the regulation, a Loan Recipient that is awarded a Company-Backed Loan shall provide warrants to CIRM equal to the lesser of 20% of Loan Recipient’s shares, fully diluted and

i. 10% of the Loan Amount if Loan Recipient shows a profit for previous 2 years;

ii. 25% of the Loan Amount -if Loan Recipient has (a) raised in prior financings since its inception three times the total amount of the loan; OR (b) has entered into a contractual arrangement (still in effect) with a biotechnology or

pharmaceutical company which requires the payment of licensing revenues or milestone payments predicated on the success of a funded project (regardless of whether it is a CIRM Funded Project); or

iii. 50% of the Loan Amount if Loan Recipient has not met either of the requirements set forth above in section C.1(a)(ii).

b. Product-Backed Loans: A Loan Recipient that is awarded a Product-Backed Loan shall provide warrants to CIRM equal to the lesser of 20% of Loan Recipient's shares, fully diluted and

- i) the amount of CIRM's contribution as a percentage of the total funds required to complete the CIRM-funded Project as set forth in the Notice of Loan Award. This allocation will be determined at the time of each loan disbursement, e.g., if CIRM's funds represent 60% of the project costs for the period covered by the first disbursement, the loan recipient would be required to provide CIRM with warrant coverage equal to 60% of the project costs during the period covered by the first disbursement; if CIRM funds represent 30% of the total project costs during the period covered by the second disbursement, then CIRM would be entitled to warrant coverage equal to 30% of the total project costs for that period.
- ii) For the purposes of Section C.1(b)(i), (ii) the "total funds required to complete the CIRM-funded Project" shall be determined as of the date of the execution of the Notice of Loan Award and shall be calculated using the indirect cost reimbursement rate specified in the Grants Administration Policy.

2. Warrant terms

If the Borrower is publicly held, the warrant strike price will be the closing price of the Borrower's common or preferred stock reported for the business day immediately before each CIRM disbursement of funds, depending upon whether CIRM selects common or preferred stock warrants. For privately held Borrowers, the warrant strike price will be set at the share price from the most recent round of equity financing before each disbursement of CIRM funds. If there has been no previous round, the warrants will be floated until the next round. The warrants are transferrable, may be

exercised at any time, and expire 10 years from the date on which they are issued. Warrants may be of either common or preferred stock, as determined by CIRM in its sole discretion.

Rationale: The amendments embody policy changes adopted by the ICOC to simplify warrant coverage terms and clarify the distinction between company-backed loans and product-backed loans. The amendments also update the schedule of warrant requirements for product-backed loans that depends on the amount of co-funding provided by the loan recipient. This provides leverage to encourage spreading of risk.

D. Risk Premium Alternative to Warrants

Purpose: The amendments add new language as an alternative to warrant coverage, providing that

In lieu of providing warrants pursuant to Subpart C of this regulation, Loan Recipients may elect to pay CIRM, as a risk premium, a multiple of the principal amount of their loan. The risk premium payment owed is based on the achievement of certain revenue thresholds.

1. **Definitions:** The following definitions shall apply to terms in this Subpart D. Capitalized terms which are undefined have the same meaning set forth in CIRM's Loan Administration Policy.

a. **Advisory Letter and Term Sheet** means correspondence issued by CIRM to the Loan Recipient identifying the sources of revenue streams that will be included in the definition of Product Revenue for Product-Backed Loans and Company-Backed Loans.

b. **Risk Premium Payment** means a payment due pursuant to Subparts "2.b" and "2.c" of this Subpart "D".

c. **Product Revenue:** see Subpart "2.d" of this Subpart "D."

2. Risk Premium Payment

a. **Election of Risk Premium Payment in Lieu of Warrants:** A Loan Recipient may elect to pay CIRM the Risk Premium Payments set forth in this Subpart "D" in lieu of providing the warrants set forth in the Loan Administration Policy.

b. **Company-Backed Loans:** Subject to the conditions set forth in Subpart "5" of this Subpart "D", the Loan Recipient of a Company-Backed Loan shall, in addition to any other obligations it has under any CIRM loan agreement or under CIRM's Loan Administration Policy (excluding the requirement to provide warrants), pay up to three hundred percent (300%) of the principal loan amount, payable upon the achievement of certain revenue thresholds as follows:

i. Upon generation of \$300 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to one hundred percent (100%) of the amount of the principal of the Company Backed Loan.

ii. Upon generation of \$600 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Company Backed Loan.

c. **Product-Backed Loans:** Subject to the conditions set forth in Subpart “2.e” of this Subpart “D”, the Loan Recipient of a Product-Backed Loan shall, in addition to any other obligations it has under any CIRM loan agreement or under CIRM’s Loan Administration Policy (excluding the requirement to provide warrants), pay up to five hundred percent (500%) of the principal loan amount, payable upon the achievement of certain revenue thresholds as follows:

i. Upon generation of \$10 million of Product Revenue in a fiscal year, Loan Recipient shall pay to CIRM an amount equal to one hundred percent (100%) of the amount of the principal of the Product-Backed Loan.

ii. Upon generation of \$300 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Product-Backed Loan.

iii. Upon generation of \$600 million of Product Revenue cumulatively, Loan Recipient shall pay to CIRM an amount equal to two hundred percent (200%) of the amount of the principal of the Product-Backed Loan.

d. **Product Revenue:**

i. Definition: Product Revenue shall be defined in accordance with an Advisory Letter and Term Sheet issued by CIRM following discussions with the Loan Recipient prior to the Loan Recipient’s submission of its application in response to a Request for Application. “Product Revenue” shall include income received by the Loan Recipient or by any joint venture or subsidiary created by Loan Recipient, including but not limited to, upfront licensing fees, development milestone payments received from a product development partner, revenues from commercial sales, or royalties on commercial sales, which arise from or are related to development and/or commercial sale of the product or service.

ii. Exclusions and Deductions: The following shall be excluded from Product Revenue in the event that they are included in the gross sales amount invoiced:

- 1) deductions for returns (including withdrawals and recalls);
- 2) rebates or price reductions for government programs (e.g., Medicaid);
- 3) volume or quantity discounts or other discounts offered at the time of invoicing; and
- 4) sales and other taxes directly linked to the gross sales amount.

In addition, Product Revenue shall exclude, to the extent such costs were incurred in connection with the sale of a product or service included in Product Revenue, any freight and postage costs, transportation insurance, packaging materials for transporting the product, customs duties, and discounts for prompt payment or similar discounts applicable after the time of invoicing.

e. Conditions and Timing of Payment:

i. Upon achievement of the revenue thresholds described in Subparts “2.b” and “2.c” of this Subpart “D,” Loan Recipient shall pay CIRM the Risk Premium Payment quarterly in equal installments over 12 months starting in the first quarter following the achievement of such revenue threshold, provided, however, that no Risk Premium Payments shall be due prior to the end of the initial term of the Loan.

ii. In the event that a Product-Backed Loan is forgiven, Loan Recipient shall have no obligation to make the Risk Premium Payments unless and until the Loan is reinstated.

iii. Pre-commercial revenues such as development milestone payments will trigger a Risk Premium Payment only in the event that the CIRM-Funded Project results in revenues from commercial sales and the revenue thresholds described in Subparts “2.b” (for Company-Backed Loans) and “2.c” (for Product-Backed Loans) of this Subpart “D” are satisfied.

3. Sunset Provision: This Subpart “D” (“Risk Premium Alternative to Warrants”) shall remain in effect until all loans made pursuant to RFA 11-02 CIRM Early Translational Awards III, RFA 10-05 CIRM Disease Team Therapy Development Awards, and any earlier requests for applications, have been issued unless this provision is earlier terminated or made permanent by subsequent action of the ICOC. Loans already entered into pursuant to this regulation shall be subject to these provisions, provided the Loan

Recipient elected to make the risk premiums set forth in this chapter in lieu of providing warrants as set forth under Subpart “C” of this policy.

Rationale: These amendments implement an alternative to warrant coverage that nevertheless provides a risk premium return to CIRM. These amendments provide the mechanism for determining the payment triggers and amounts that will be due CIRM under this program.

H. Forgiveness and Reinstatement of Product-Backed Loans

Purpose: The amendments replace existing language and provide that (1) A Product-Backed Loan shall be automatically forgiven in the event that all of the following have been satisfied:

- (a) The Borrower has complied with all reporting requirements;
- (b) The Borrower abandons the CIRM-Funded Project during the Loan Period, submits a declaration to this effect and does not resume work on such Project, or CIRM terminates the Project; and
- (c) To the extent that the Borrower obtains revenue arising in whole or in part from the CIRM-Funded Project in an amount less than the amount of the loan, the Borrower has repaid CIRM the principal and interest on the loan up to the amount of revenue generated

(2) Notwithstanding subpart (1) above, a Loan which has been forgiven will automatically be reinstated in the event that the Borrower obtains revenue arising in whole or in part from the CIRM-Funded Project. If the Borrower’s obligation to repay has been forgiven and if further activity results in a repayment obligation under this provision, the Product-Backed Loan Recipient must promptly notify CIRM. The Product Backed Loan will automatically be reinstated under terms that the Finance Subcommittee shall approve, except that in no event will the interest rate be higher than the per annum rate equal to LIBOR for a one-year deposit in U.S. dollars, as published by the Wall Street Journal (or if the Wall Street Journal is not available, a comparable source) on the date of reinstatement plus 2%. The Principal and interest owed shall be reduced by any amount previously repaid to CIRM prior to forgiveness. Upon reinstatement of the Loan, the Product-Backed Loan Recipient shall be eligible for subsequent forgiveness and reinstatement in accordance with the terms of this section.

Rationale: The amendments are necessary to provide clarity regarding automatic forgiveness mechanisms for product-backed loans with an automatic reinstatement when work described in the loan award is resumed. Reinstatement will be on terms approved by the Finance Subcommittee, providing flexibility to CIRM to account for potentially changed circumstances. These amendments ensure CIRM is able to capitalize on any revenue generated as a result of its funding – regardless of whether a loan has been forgiven in the past.

K. Loan Application Process

Purpose: The amended language provides that:

1. CIRM Loan Application Form

By the application deadline for an RFA that offers Loan funding, a Loan applicant must submit a Loan application form. The applicant must indicate its preference for a Product-Backed or Company-Backed loan. The Loan Applicant will be required to submit financial information, pursuant to CIRM's or its agents' request. CIRM's Governing Board may decline to award a Loan on one or more legal or financial grounds, including but not limited to risk of attachment, bankruptcy, or insolvency, or failure to meet industry standards for financial practices or adhere to generally accepted accounting principles.

2. Scientific Review

Loan applications will be subject to the same scientific review by the Grants Working Group as a Grant application, and final determination of scientific merit by the ICOC.

3. Financial Feasibility Review

CIRM will assign each Loan applicant (or Borrower) to a Financial Services Provider. Each applicant or Borrower will work directly with a Financial Services Provider to provide the financial and business information that the Financial Services Provider needs to evaluate the applicant's ability to manage and repay CIRM funds. CIRM will deduct the costs of the financial due diligence from the indirect costs awarded to the Loan Recipient.

Rationale: These amendments are necessary to simplify the process of applying for a loan and clarifying the criteria upon which a loan will be evaluated and alerting the potential borrower to costs associated with the evaluation process.

Findings and Declarations

Technical, Theoretical or Empirical Studies, Reports or Documents:

A. Documents or Laws:

None.

B. Public Input:

Discussion and public input received at public meetings conducted by the Finance Subcommittee on April 18, 2011, and the ICOC on May 3 and 4, 2011.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107. Transcripts and meeting minutes of the meetings referenced in Section “B” are available on CIRM’s website, www.cirm.ca.gov under the “Meetings Transcripts” and “Meetings Minutes” links.

Reasonable Alternatives to the Regulation and the Agency’s Reasons for Rejecting Those Alternatives:

CIRM determined that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business:

CIRM has not identified any alternatives that would lessen any adverse impact on small businesses.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business:

The proposed regulation amendment imposes no restrictions or obligations on businesses. The regulation action expands the materials eligible for use in CIRM-funded research.

*****End*****